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Innovative Technology for Smart Therapy

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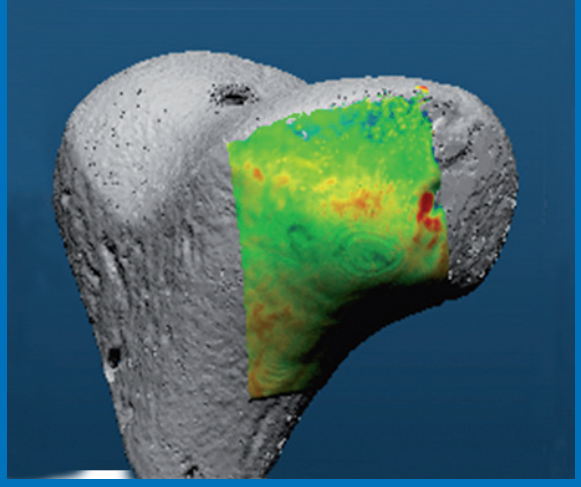

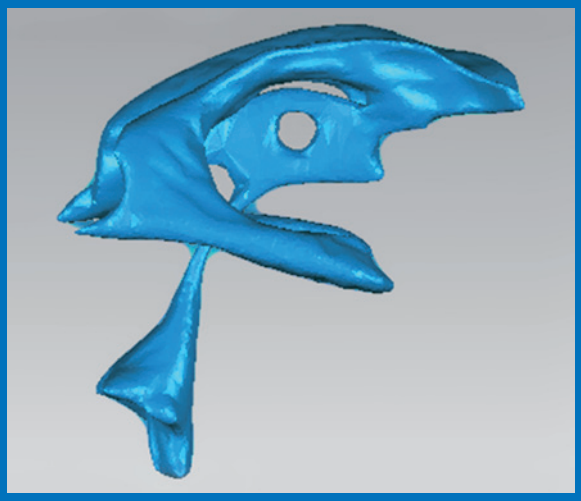

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Introduction

Demographic changes and the related need for efficiency in public health care are actually driving factors in biomedical engineering research. Anyhow, advanced engineering methodology and modern technologies support the trend towards personalized solutions for an optimized therapy of each individual patient. Due to an optimal restoration and preservation of workability, mobility and autonomy, patients' quality of life based on an enhanced therapeutic effectiveness, potentially comes along with socio-economic efficiency of public health care. For more than two decades our work has been dedicated to this trend of personalized therapy with a special focus on computer assisted model guided therapy. Linking basic research with application-oriented development and evaluation, our activities cover different aspects – from the acquisition, segmentation and reconstruction of relevant information, its registration and integration for patient specific modelling and planning, to adequate technical means for model guided action (Fig. 1). Last but not least, integration including risk management and usability engineering of medical systems, representing essential factors of success for the transfer to clinical application, is another focus area of our work.

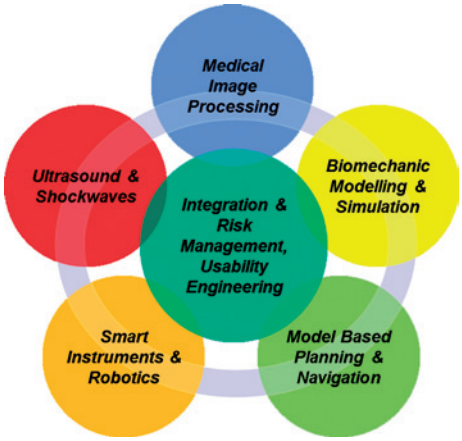


Fig. 1: Focus research areas and teams at mediTEC.

The coordination of the OR.NET project on secure dynamic integration of modular OR-systems, a flagship project of the German Ministry for Education and Research (BMBF) with an overall budget of 18,5 M€ (2012-8/2015), 54 full partners and meanwhile more than 40 associated partners from industry, academia, clinics and associations, certainly represented a major challenge in 2014. The project enables us to continue our research on technology, risk management and usability of integrated OR-systems and assure sustainability on a national and international level - amongst others - based on international standardization activities.
Based on the results of our preliminary work in the framework of the BMBF project IDA (development of an intraoral ultrasound based micro-scanner; Medical Technology Innovation Award 2008 of the BMBF) the related IDentUS spin-off initiative has been set forth very successfully. The team received a substantial EXIST spin-off grant of the Federal Ministry of Economic Affairs and Energy (BMWi) starting in April 2014 and won the Pitch Contest of the Aachen Technology and Entrepreneurship Conference in October 2014. Thereby, we are optimistic, that another example of successful transfer of basic research and development results to its clinical application is on the way. Moreover, we were happy to mentor the young team of the DESINO GmbH (www.desino.eu) developing innovative wheel chairs and to support their work in the area of biomechanics and simulation.

Fig. 2: Internal OR.NET status symposium 2014, Aachen

The RapidGEN project on personalized modeling and rapid manufacturing of patient specific knee implants (2,3 M€ co-funded by the state of North-Rhine Westphalia and by the European Union as part of the European Regional Development Fund; 7 Partners, Coordination: mediTEC) is another example of our actual flagship projects. It is the basis for continuing research and developments in cooperation with our medical and industrial partners. Additionally, various projects related to basic research issues (e.g. funded by the German Research Foundation (DFG)) as well as industrial co-operations in different focus areas have been pursued by our team. International publications of our research, the market applications of products originally developed in our lab as well as international patent applications annually confirm our general concept of combining basic as well as problem oriented medical engineering research and application development, being also an essential basis for a sound education of our students.
Last but not least, we have to confess, that our scientific achievements have been outshined by the extraordinary performance of the mediTEC "Health Bells", who delivered 1st class music to the spoiled ears of the distinguished HIA community – certainly one of the cultural highlights of 2014!

Fig. 3: mediTEC Health Bells backstage - with their director of arts Sabine Stockschläder-Krüger, M.A. (on the left).

Selected Projects

Image and model-based reconstruction of the bony knee anatomy

Ultrasound offers high resolution images of soft and hard tissue in real-time while being cost-efficient and broadly available. Its weaknesses, however – in contrast to CT or MRI - , are a low signal to noise ratio (SNR), speckle, and bone shadowing. Therefore, new methods must be developed to extract information from the ultrasound data such as the surfaces of bone or cartilage. We are developing a work flow and image processing chain to reconstruct bony surfaces of the knee joint (Fig. 4).

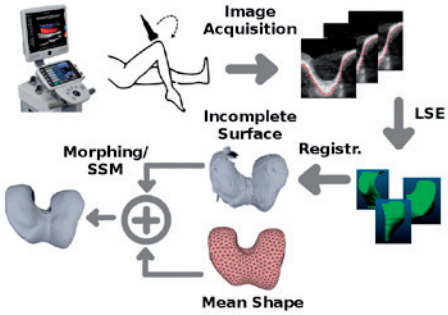


Fig. 4: Excerpt of the processing chain for ultrasound based bone reconstruction of the knee joint.

This is done by extracting surface patches from 3D ultrasound volume images which are then co-registered. This yields an incomplete and erroneous surface which can be reconstructed using statistical shape models. The result is a reconstruction with a resolution similar to that if reconstructed from CT or MRI images. Optionally this information can be registered to 2D standard plain x-ray images in order to identify e.g. the mechanical leg axis (Fig. 5).

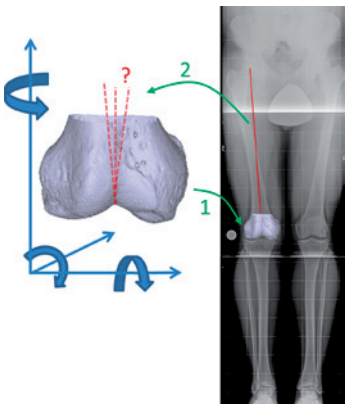


Fig. 5: Determination of the mechanical axis using 3D-2D registration of 3D-US data and standard 2D x-ray images.

Patient-Specific modelling of the knee

Musculoskeletal models have the potential to predict dynamic interactions of the knee joint and provide insights into knee biomechanics for morphological analyses and optimization of surgical interventions. The development of validated algorithms enabling semi-automatic patient specific adaptation of MBS (multi body simulations) models including soft- and hard-tissue structures and their clinical application are some key objectives of our research.

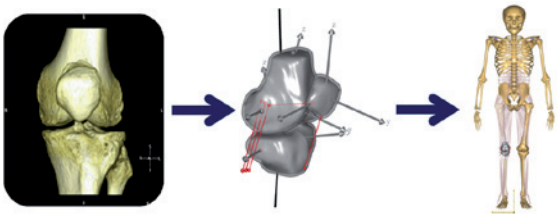


Fig 6: Development of a patient-specific simulation model of the knee based on CT- imaging.

With our new PCA knee testing rig for experimental phantom as well as human specimen tests we are able to investigate active and passive kinematics of physiological knees or artificial knee implants. Results can be used for optimization and validation of multi-body simulation models.

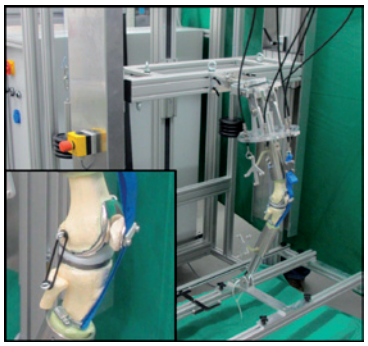


Fig. 7: PCA knee testing rig with a modular testing leg.

Biomechanical modelling for hip surgery

A consideration of the patient specific biomechanical situation in the context of the surgical planning of total hip arthroplasty is highly recommended and may have a positive impact on the therapeutic outcome. We evaluated biomechanical models proposed by Pauwels, Debrunner, Blumentritt and Iglič comparing the calculated resultant hip forces R with in-vivo data from instrumented prostheses from the OrthoLoad-database. Whereas the absolute value of R calculated on the basis of the models of Pauwels, Debrunner and Iglič showed good agreement with the in-vivo data, the Blumentritt model showed abnormally high results. The computational results showed large variations for the orientation of R which tend to depend more on the model used than on patient-specific parameters.

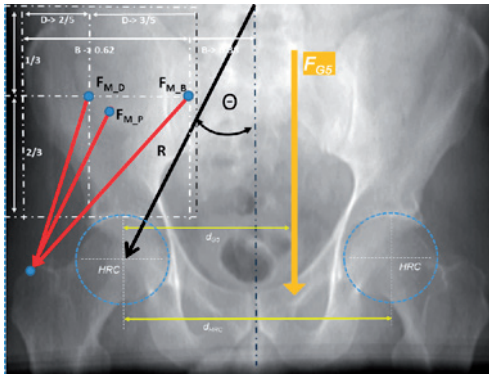


Fig. 8: Anatomical landmarks of different biomechanical models of the hip joint.

Biomechanical modelling of the wrist joint for patient specific model guided surgical therapy

We developed, implemented and tested an enhanced musculoskeletal biomechanical multi-body simulation model for therapy planning in the context of wrist joint surgery together with an experimental testing rig for the evaluation of simulation results with human specimens. A comprehensive ligamentous apparatus was implemented in the MBS model enabling the investigation of ligament function. It can be easily personalized on the basis of image information of the individual patient. The model enables a simulation of individual wrist motion and predicts trends correctly in case of changing kinematics (e.g. ligament ruptures or surgical therapies).

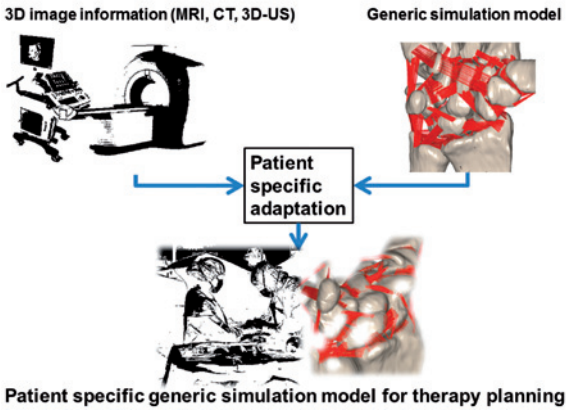


Fig. 9: Generic concept of patient specific model driven wrist surgery.

Biomechanics of hydrocephalus

The symptoms of Normal Pressure Hydrocephalus range from dementia to gait disturbance and incontinence. The patients suffer from irreversible damage of brain tissue, whose origin is not clearly understood yet. However, biomechanical factors due to aging tissues seem likely. Therefore different experimental and computer based biomechanical models are developed in order to understand the onset of the disease better and by doing so accomplish more adequate treatment options.

Intraoral dental scanning using ultrasound

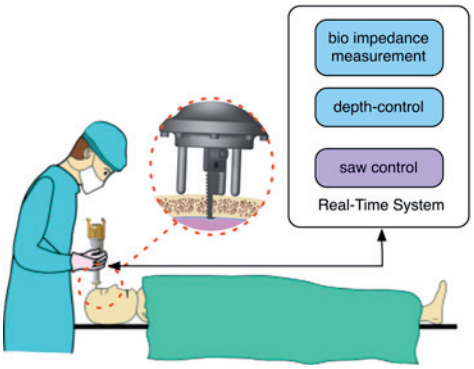
Dental impressioning is often affected by soft-tissue, blood and saliva regardless whether using compound impression techniques or digital optical scanning methods. In contrast, ultrasonic waves are able to non-invasively penetrate gingiva, saliva and blood leading to decisive advantages as cleaning and drying of the oral cavity becomes needless. The application of ultrasound may facilitate the detection of subgingival structures without invasive manipulation.
The objective of the BMWi EXIST project IDentUS is the development and implementation of an ultrasound-based intraoral micro-scanner, replacing the conventional impression without the drawbacks of current optical scanners. In addition, suitable business models and strategies for a market entry with our ultrasound technology are being developed.

Fig. 10: IDentUS - Intraoral Dental Ultrasound Scanning.

SICOSI – Smart Impedance Controlled Osteotomy Instrumentation

Efficient cutting of the bone and a good protection of adjacent sensitive soft tissue structures is crucial in many surgical applications. Two procedures of high relevance in this area are craniotomy and resternotomy. In both cases a bicortical bone is cut, while underlying sensitive structures have to be protected. To support the surgeon during osteotomies many active hand held instruments and robotic systems were developed. These semiautomatic instruments or automatic robots process the bone on the basis of pre- or intraoperative acquired imaging data (e.g. CT, ultrasound). The main disadvantage of these approaches is the complex integration into the medical standard workflow.

Fig. 11: SICOSI – Impedance controlled osteotomy.

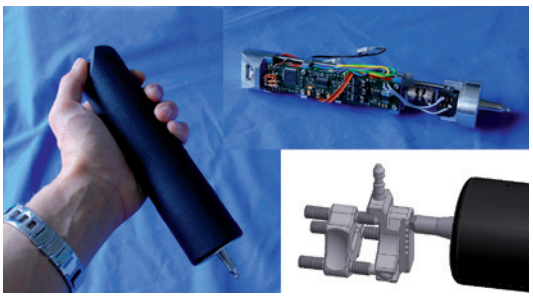


The main objective of the SICOSI project (funded by the German Research Association (DFG)) is the investigation of the feasibility of novel hand guided, sensor integrated instrument for resternotomy and craniotomy. The concept is based on online bio-impedance measurements during the cutting process and active fault tolerant control of the instrument while keeping the surgeon in the loop.

Smart Screw Driver for automatic adjustment of passive implantation guides

The correct adjustment of instrument guides according to a defined computer based plan is an essential step in computer aided surgery. One possibility studied at our institute is the semiautomatic adjustment of passive instrument or implantation guides by a handheld Smart Screw Driver (SSD). A first prototype of the SSD has been developed. The computer controlled identification of different screws for the adjustment of a passive surgical guidance device has been implemented and tested. The measuring and computing of the ID signal as well as the motor control are realized on a microcontroller on PCB boards, which communicates wireless with the computer. User guidance and interaction is enabled via the central computer as well as on-tool interfaces. The accuracy of adjustment using this SSD has been evaluated in the laboratory and is comparable to robotic devices.

Fig. 12: First Prototype of a Smart Screw Driver for automatic adjustment of passive implantation guides.



Improvement of in-vitro test setups for shockwave therapy and lithotripsy

Shockwaves are used in medicine for the comminution of stones especially in the urinary system as well as for the regeneration of biological tissues. Numerous experimental studies investigating underlying effects and evaluating new technical developments have been reported. However, our studies show that differing setup designs may have a significant impact on the experimental results as physical effects such as reflection, diffraction or cavitation modify the sound field in the target area. Therefore, one of our aims is the improvement and standardization of experimental setups towards insignificant sound field influences while ensuring realistic experimental conditions.

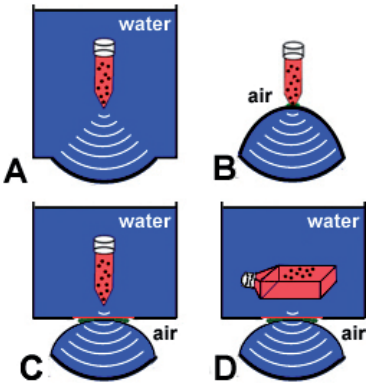


Fig. 13: Experimental setups used for in-vitro shockwave therapy.

Usability of neurofeedback therapy for home application

EEG based Neurofeedback is an alternative treatment for attention deficit hyperactivity disorder (ADHD). It enables the patient to deliberately regulate his or her own brain activity by moving a visual signal in a predetermined direction. In order to optimize the treatment by relocating it into the home environment of the patient, a headset which reproducibly places EEG electrodes on the defined positions on the head is developed. The current prototype consists of a new frame with seven electrode adapters which can be easily and robustly adapted to the individual patient.

Fig. 14: New headset for the reproducable placement of electrodes for neurofeedback therapy.

OR.NET – Plug & Play in the OR and clinic

In today's operating rooms there are numerous medical devices from many different vendors, most of which operate autonomously. Yet, data exchange between the systems and the possibility of universal control of medical devices from central user interfaces can be beneficial for the OR workflow and therefore the therapeutic outcome. Within the OR.NET project concepts for an open and secure dynamic networking of medical devices and IT systems are currently being developed and evaluated. For risk management and usability assurance of independent devices in clinical networks the development and standardization of medical device and service profiles containing technical specifications, intended use, use scenarios, network risks and Medical Device User Interface Profiles (MDUIP)

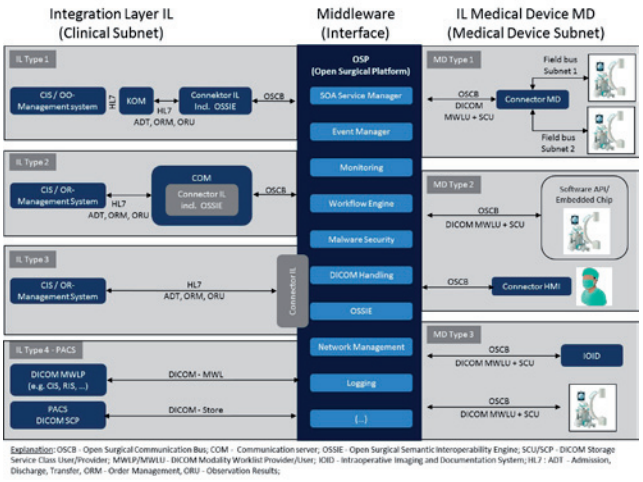


Fig. 15: a) OR.NET Integration Concept (for more details visit www.ornet.org) and b) lab-setup (Photo: Peter Winandy).

is one essential aspect of the overall OR.NET concept. MDUIPs should enable manufacturers to validate their devices against a common standard, while clinical operators will have access to relevant information for (human) risk and usability assessment of integrated OR devices and systems. The MDUIP concept has already been evaluated in cooperation with notified bodies and independent test institutes on the basis of neurosurgical use scenarios and the exemplary integration of an ultrasound dissector and an OR microscope.

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- the European Union, the Ministry of Innovation, Science, Research and Technology and the Ministry of Economic Affairs North-Rhine-Westphalia (EFRE/Ziel2.NRW)
- European Space Agency (ESA)
- ERS@RWTH Aachen

Note: In this report we can only provide a short overview of selected activities. For further information on the related projects, our cooperating partners, funding agencies and sponsors, please visit our website ***www.meditec.rwth-aachen.de*** or contact us directly.

Selected Publications

[1] F. Chuembou Pekam, J. Marotti, S. Wolfart, J. Tinschert, K. Radermacher & S. Heger. High-frequency Ultrasound as an Option for Scanning of Prepared Teeth: an in vitro Study - Ultrasound in Medicine and Biology, Vol. 41, pp. 309 - 316, 2015.

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Team

Fig. 16: mediTEC-Team members @ mediTEC winterschool 2014, Hirschegg, Austria.